

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Graeme Semple et al.

Serial No.: 10/535,345

Group Art Unit: Not Yet Assigned

Filing Date: February 15, 2006

Examiner: Not Yet Assigned

Title: Tetrazole Derivatives and Methods of Treatment of Metabolic-Related Disorders Thereof

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ before the mailing date of a first Office Action on the merits.
- ☐ after the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:

- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ after the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see "Statement," and "Fees" below).
- ☒ Copies of the references listed on the attached PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449 are enclosed.

EXCEPT THAT:

- ☒ In view of the voluminous nature of reference citations **AW-BE**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

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- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
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- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b) as no first Official Action on the merits has been received by Applicants.

Respectfully submitted,



Michael P. Straher, Ph.D.
Registration No. 38,325

Dated: April 5, 2006

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Complete if Known

Application Number	10/535,345
Filing Date	February 15, 2006
First Named Inventor	Graeme Sample
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	79 US2 PCT

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date/Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	AA	WO 2004/032928	04-22-2004	Arena Pharm		
	AB	EP 0529854	03-03-1993	Ortho Pharm		
	BR	WO 2005/016867	02-24-2005	Smithkline		
	BS	WO 2005/016870	02-24-2005	Smithkline		
	BT	WO 2005/077950	08-25-2005	Smithkline		
	BU	WO 2004/033431	04-22-2004	Arena Pharm		
	BV	WO 2005/011677	02-10-2005	Arena Pharm		

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Signature**

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT BY APPLICANT**

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Sheet 2 of 5

Complete if Known

Application Number	10/535,345
Filing Date	February 15, 2006
First Named Inventor	Graeme Semple
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	79.US2.PCT

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AC	Le Bas et al., "Radioiodinated analogs of EP 00652218 for the exploration of the tachykinin NK1 receptor by spect," <i>J. Labelled Cpd. Radiopharm.</i> (2001) 44(Suppl 1):S280-S282.	
	AD	Bays et al., "Pharmacotherapy for dyslipidaemia--current therapies and future agents," <i>Expert Opinion on Pharmacotherapy</i> (2003) 4(11):1901-1938.	
	AE	Chang et al., "Ciglitazone, a new hypoglycemic agent. I. Studies in ob/ob and db/db mice, diabetic Chinese hamsters, and normal and streptozotocin-diabetic rats," <i>Diabetes</i> (1983) 32:830-838.	
	AF	Collier et al., "Radiosynthesis and in-vivo evaluation of the pseudopeptide δ -opioid antagonist [¹²⁵ I]-ITIPP(Ψ)," <i>J. Labelled Cpd. Radiopharm.</i> (1999) 42(Suppl 1):S264-266.	
	AG	Coleman "Diabetes-obesity syndromes in mice," <i>Diabetes</i> (1982) 31(Suppl 1):1-6.	
	AH	Coleman et al., "Fat (fat) and tubby (tub): two autosomal recessive mutations causing obesity syndromes in the mouse," <i>J. Heredity</i> (1990) 81:424-427.	
	AI	Cornhill et al., "Topographic study of sudanophilic lesions in cholesterol-fed minipigs by image analysis," <i>Arteriosclerosis, Thrombosis and Vascular Biology</i> (1985) 5(5):415-426.	
	AJ	Delporte et al., "Pre- and post-translational negative effect of beta-adrenoceptor agonists on adiponectin secretion: in vitro and in vivo studies," <i>Biochem Journal</i> (2002) 367:677-85.	
	AK	Eriksson et al., "Increased incidence of congenital malformations in the offspring of diabetic rats and their prevention by maternal insulin therapy," <i>Diabetes</i> (1982) 31:1-6.	
	AL	Friedman et al., "Tackling a weighty problem," <i>Cell</i> (1992) 69:217-220.	
	AM	Gerrity et al., "Diabetes-induced accelerated atherosclerosis in swine," <i>Diabetes</i> (2001) 50(7):1654-1665.	

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Application Number	10/535,345
Filing Date	February 15, 2006
First Named Inventor	Graeme Sample
Art Unit	To Be Determined
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NON PATENT LITERATURE DOCUMENTS

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	AN	Guyton "Effect of niacin on atherosclerotic cardiovascular disease," <i>Am. J. Cardiol.</i> (1998) 82:18U-23U.	
	AO	Koranyi et al., "Glucose transporter levels in spontaneously obese (db/db) insulin-resistant mice," <i>J. Clin Invest</i> (1990) 85:962-967.	
	AP	Lorenzen et al., "Characterization of a G protein-coupled receptor for nicotinic acid," <i>Molecular Pharmacology</i> (2001) 59(2):349-357.	
	AQ	Lorenzen et al., "G protein-coupled receptor for nicotinic acid in mouse macrophages," <i>Biochemical Pharmacology</i> (2002) 64:645-648.	
	AR	Matsuda et al., "Role of adiponectin in preventing vascular stenosis. The missing link of adipovascular axis," <i>J. Biol. Chem.</i> (2002) 277(40):37487-91.	
	AS	Royo et al., "Effect of gemfibrozil on peripheral atherosclerosis and platelet activation in a pig model of hyperlipidemia," <i>Eur J Clin Invest.</i> (2000) 30(10):843-52.	
	AT	Truett et al., "Rat obesity gene fatty (fa) maps to chromosome 5: evidence for homology with the mouse gene diabetes (db)," <i>Proc. Natl. Acad. Sci. USA</i> (1991) 88(17):7806-7809	
	AU	Zhu et al., "Synthesis and mode of action of (125)I- and (3)H-labeled thieno[2,3-c]pyridine antagonists of cell adhesion molecule expression," <i>J. Org. Chem.</i> (2002) 67:943-948.	
	AV	Goodman and Gilman's Pharmacological Basis of Therapeutics, editors Harmon JG and Limbird LE, Chapter 36, Mahley RW and Bersot TP (2001) pp. 971-1002.	
	*AW	Hudlicky, <i>Oxidations in Organic Chemistry</i> , ACS Monograph 186 (1990).	
	*AX	Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, Tenth Edition (1983).	

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Sheet 4 of 5

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	*AY	Smith et al., <i>Advanced Organic Chemistry</i> (2001) 5 th Edition, Wiley-Interscience.	
	*AZ	Larock, <i>Comprehensive Organic Transformations, A Guide to Functional Group Preparations</i> , 2 nd Edition, VCH Publishers, Inc. (1999).	
	*BA	Wuts et al., <i>Protective Groups in Organic Synthesis</i> , 3 rd Edition, John Wiley and Sons (1999).	
	*BB	Jacques et al., <i>Enantiomers, Racemates and Resolutions</i> (1981) John Wiley and Sons, New York.	
	*BC	Remington, <i>The Science and Practice of Pharmacy</i> (2000) 20 th Edition, Lippincott Williams & Wilkins (Editors: Gennaro et al.)	
	*BD	Higuchi et al., "Pro-drugs as novel delivery systems," Vol. 14 of the A.C.S. Symposium Series.	
	*BE	Bioreversible Carriers in Drug Design, ed. Edward B. Roche, American Pharmaceutical Association and Pergamon Press (1987).	
	BF	Shafir "Diabetes in Animals," <i>Diabetes Mellitus</i> , Rifkin et al., Eds [Elsevier Science Publishing Co., New York, ed. 4, (1990) pp.299-340.]	
	BG	Horikoshi et al., "Troglitazone (CS-045), a new Antidiabetic Drug," <i>Annu Rep Sankyo Res Lab</i> (1994) 46:1-57.	
	BH	ElAmin et al., "Removal of benzyl-type protecting groups from peptides by catalytic transfer hydrogenation with formic acid," <i>J Org Chem</i> (1979) 44(19):3442-3444.	
	BI	Flechner-Mors et al., "Effects of acipimox on the lipolysis rate in subcutaneous adipose tissue of obese subjects," <i>Diabetes/Metabolism Research and Reviews</i> (2001) 17:387-390.	

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NON PATENT LITERATURE DOCUMENTS

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	BJ	Haddach et al., "An efficient method for the N-debenzylation of aromatic heterocycles," <i>Tetrahedron Letters</i> (2002) 43:399-402.	
	BK	van Herk et al., "Pyrazole derivatives as partial agonists for the nicotinic acid receptor," <i>J Med Chem</i> (2003) 46:3945-3951.	
	BL	Holland et al., "Heterocyclic tetrazoles, a new class of lipolysis inhibitors," <i>Journal of Medicinal Chemistry</i> (1967) 10:149-154.	
	BM	Krynitsky et al., "2-Ethylhexanonitrile," <i>Organic Syntheses, Coll.</i> (1963) 4:436.	
	BN	Soga et al., "Molecular identification of nicotinic acid receptor," <i>Biochemical and Biophysical Research Communications</i> (2003) 303:364-369.	
	BO	Surrey "Malononitrile," <i>Organic Syntheses, Coll.</i> (1955) 3:535.	
	BP	Tunaru et al., "PUMA-G and HM74 are receptors for nicotinic acid and mediate its anti-lipolytic effect," <i>Nature Medicine</i> (published online 3 Feb 2003) 1-4.	
	BQ	Wise et al., "Molecular identification of high and low affinity receptors for nicotinic acid," <i>The Journal of Biological Chemistry</i> (2003) 278(11):9869-9874.	

Examiner Signature		Date Considered	
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